

**VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT
AUF DEM GEBIET DES PATENTWESENS**

PCT

INTERNATIONALER VORLÄUFIGER PRÜFUNGSBERICHT

REC'D 16 SEP 2003

WIPO PCT

(Artikel 36 und Regel 70 PCT)

(Rationalisierter Bericht gemäß Beschluß des Präsidenten des EPA veröffentlicht im ABI 11/2001)

Aktenzeichen des Anmelders oder Anwalts LEA35906-WO	WEITERES VORGEHEN siehe Mitteilung über die Übersendung des internationalen vorläufigen Prüfungsberichts (Formblatt PCT/IPEA/416)	
Internationales Aktenzeichen PCT/EP 03/ 03180	Internationales Anmeldedatum (Tag/Monat/Jahr) 27/03/2003	Prioritätsdatum (Tag/Monat/Jahr) 08/04/2002
Internationale Patentklassifikation (IPK) oder nationale Klassifikation und IPK C07C51/377		
Anmelder BAYER CROPSCIENCE AKTIENGESELLSCHAFT et al		

1. Der internationale vorläufige Prüfungsbericht wurde von der mit der internationalen vorläufigen Prüfung beauftragten Behörde erstellt und wird dem Anmelder gemäß Artikel 36 übermittelt.


2. Dieser **BERICHT** umfaßt insgesamt 2 Blätter einschließlich dieses Deckblatts.

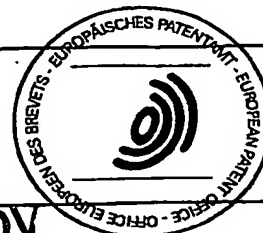
☐ Außerdem liegen dem Bericht **ANLAGEN** bei; dabei handelt es sich um Blätter mit Beschreibungen, Ansprüchen und/oder Zeichnungen, die geändert wurden und diesem Bericht zugrunde liegen, und/oder Blätter mit vor dieser Behörde vorgenommenen Berichtigungen (siehe Regel 70.16 und Abschnitt 607 der Verwaltungsvorschriften zum PCT)

Diese Anlagen umfassen insgesamt _____ Blätter.

3. Dieser Bericht enthält Angaben und die entsprechenden Seiten zu folgenden Punkten:

- I ☒ Grundlage des Berichts
- II ☐ Priorität
- III ☐ Keine Erstellung eines Gutachtens über Neuheit, erfinderische Tätigkeit und gewerbliche Anwendbarkeit
- IV ☐ Mangelnde Einheitlichkeit der Erfindung
- V ☒ Begründete Feststellung nach Artikel 35(2) hinsichtlich der Neuheit, der erfinderischen Tätigkeit und der gewerblichen Anwendbarkeit; Unterlagen und Erklärungen zur Stützung dieser Feststellung
- VI ☐ Bestimmte angeführte Unterlagen
- VII ☐ Bestimmte Mängel der internationalen Anmeldung
- VIII ☐ Bestimmte Bemerkungen zur internationalen Anmeldung

Datum der Einreichung des Antrags 28/08/2003	Datum der Fertigstellung dieses Berichts 09/09/2003
Name und Postanschrift der mit der internationalen vorläufigen Prüfung beauftragten Behörde  Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Niederlande Tel.: (+31-70) 340-2040 Fax: (+31-70) 340-3016	Bevollmächtigter Bediensteter VERHULST W Tel. (+49-89) 2399 2828



I. Grundlage des Berichts

Grundlage dieses Berichtes sind die Anmeldungsunterlagen in der ursprünglich eingereichten Fassung.

V. Begründete Feststellung nach Regel 66.2(a)(ii) hinsichtlich der Neuheit, der erfinderischen Tätigkeit und der gewerblichen Anwendbarkeit

In Anbetracht der im internationalen Recherchenbericht angeführten Unterlagen wird festgestellt, daß die Erfindung, wie sie in den Ansprüchen gekennzeichnet ist, die in Artikel 33(1) PCT aufgeführten Kriterien erfüllt, d.h. als neu, als auf erfinderischer Tätigkeit beruhend und als gewerblich anwendbar anzusehen ist.

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference LEA35906-WO	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP03/03180	International filing date (day/month/year) 27 March 2003 (27.03.03)	Priority date (day/month/year) 08 April 2002 (08.04.02)
International Patent Classification (IPC) or national classification and IPC C07C 51/377, 51/093, 57/30, 59/48, 45/46, 49/233		
Applicant BAYER CROPSCIENCE AKTIENGESELLSCHAFT		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☐ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 28 August 2003 (28.08.03)	Date of completion of this report 24 June 2003 (24.06.2003)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP03/03180

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
 pages 1-16, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☒ the claims:
 pages 1-13, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☒ the drawings:
 pages 1/1, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☒ the sequence listing part of the description:
 pages 1-6, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP03/03180

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☒ the entire international application.

☐ claims Nos. _____

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1,2,4-7,9-11
are so unclear that no meaningful opinion could be formed (*specify*):

See supplemental Box.

☒ the claims, or said claims Nos. 1,2,4-7,9-11 are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 3,8,12.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.1

Box III

**Non-establishment of opinion with regard to novelty,
inventive step and industrial applicability**

This report makes reference to the following international search report citations (D), the same numbering will be used in further proceedings:

- D1: DATABASE ON-LINE MEDICAL DICTIONARY [Online]
12 December 1998 (1998-12-12)
- D2: FATTORUSO, V ET AL: 'Vademecum Clinique', 2001,
MASSON, PARIS
- D3: WO-A-00/62781 (WALDEGGER SIEGFRIED; BROEER STEFAN
(DE); KLINGEL KARIN (DE); LANG) 26 October 2000
(2000-10-26) mentioned in the application.

- 1 Claims 3, 8 and 12 were not researched, because they do not comply with the requirements of PCT Rule 5.2. It is therefore impossible to assess the novelty, inventive step and industrial applicability of these claims.
- 2 The technical problem addressed by this application is that of detecting hypertonia experimentally by correlation with a marker protein or a polymorphism. However, Claims 1, 2, 4 to 7, 11 and 13 do not provide a solution to this problem: the detection of hypertonia (**systolic blood pressure of at least 140 mmHg; diastolic blood pressure of at least 90 mmHg**, see D1 or D2) requires a marker protein or a polymorphism whose presence in a patient represents an incontestable correlation with such a blood pressure. Since the alleged correlation between the polymorphism C-> T in Exon 8 of human homologues of the sgk family or the overexpression of the protein

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.1

product and the hypertonia was not shown to lie within the above-mentioned blood pressure range, the subject matter of Claims 1, 2, 4 to 7, 11 and 13 does not solve the technical problem.

In the light of D1 and D2, doubts therefore arise as to the technical feasibility of the application and the requirements of PCT Articles 5 and 6 are apparently not satisfied: there is neither support nor complete disclosure that would enable a person skilled in the art to diagnose hypertonia.

It is therefore impossible to assess the novelty, inventive step and industrial applicability of Claims 1, 2, 4 to 7, 11 and 13.

- 3 Even if the above-mentioned defects could be rebutted, the present application would, in fact, still not comply with the requirements of PCT Article 33 for the following reasons:

3.1 Document D3 (page 3, lines 1 to 4), which is regarded as the closest prior art, describes that increased expression of human sgk results in hypertonia. It therefore seems that, if a correlation really exists between overexpression of the hsgk protein and hypertonia, Claims 1, 2, 10 and 11 cannot be regarded as novel, and Claims 1, 2, 5, 7, 10 and 11 do not involve an inventive step (the production of a corresponding kit is regarded as obvious for a person skilled in the art).

3.2 Claims 1, 2 and 4, which relate to the use of such a correlation, describe a mathematical method (PCT Rule 39.1(i)) and Claims 10, 11 and 13 a diagnostic method

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP 02/03180

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.1

which comprises steps that are performed on the human body (PCT Rule 39.1(iv)). Not all the PCT Contracting States (e.g., the EPC States) would regard such claims as industrially applicable within the meaning of PCT Article 33(4).

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